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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,226	03/25/2004	Julie Dyall	3219/7	6542

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EXAMINER	
HORNING, MICHELLE S	
ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
02/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/809,226	DYALL ET AL.	
	Examiner	Art Unit	
	Michelle Horning	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 11-26* is/are pending in the application.

4a) Of the above claim(s) *12-15, 19-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 11, 16-18, 22-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is responsive to communication filed 1/4/2008. The status of the claims is as follows: claims 1, 11, 16-18 and 22-26 are under current examination. Please note that the finality of the last office action dated 11/27/2007 is withdrawn in view of the rejections below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 11, 16-18 and 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over PG Pub No: 2002/0034732 (hereinafter as "Capon", cited) and Olivo et al (1998, cited). Capon et al discloses a method for determining the susceptibility for an HCV (hepatitis C virus) antiviral drug or HCMV (human cytomegalovirus) antiviral drug. This method comprises the following steps: a. introducing a resistance test vector comprising a patient-derived segment and an indicator gene into a host cell; b. culturing the host cell; c. measuring the expression of the indicator gene in a target host cell; and d. comparing the expression of the indicator gene either in the presence or absence of an antiviral drug (see Abstract). Additionally, the authors make the following recitation: "This invention also provides a method for evaluating the biological effectiveness of a candidate HCV or HCMV anti-viral drug compound" (see Abstract). This prior art reference discloses that a test vector may be

delivered to the host cell at the time of infection or may be stably integrated into the target host cell chromosomal DNA (see paragraph 95); this teaching meets the limitations of claims 22-23 of the instant specification. Host cells are discussed in paragraph 120 and can be derived from human tissues, including hepatocytes, meeting the limitations of claim 24 of the instant specification. Lastly, Capon et al teach that RT-PCR is a sensitive method that can be used to detect replication *in vitro* expression systems (see whole document, including paragraph 20 and Example 12); see claims 16-18 of the instant specification which are drawn to amplification of nucleic acid by RT-PCR. The authors do not disclose the following: the act of combining the first and second cell cultures with or without a third culture, each containing separate subgenomic viral replication systems; candidate antiviral agents including an organic chemical that does not comprise an oligopeptide or an oligonucleotides or does comprise an oligopeptide or an oligonucleotide; and incubation of the cell cultures for at least 20 hours.

It would have been obvious for one of ordinary skill in the art to incubate the cell cultures with a candidate antiviral agent at varying durations. One would have been motivated to do so in order to determine what the incubation times would be optimal for differential drugs in producing an antiviral effect. The ordinary artisan would have not limited the scope of drugs in the screening method to any particular drug in order to increase the success of finding an antiviral compound by testing all types. Further, it would have been obvious for the ordinary artisan to screen for antiviral effects of a single drug on cell cultures containing cells infected with multiple subgenomic viral

replication systems. One would have been motivated to do so in order to efficiently determine the antiviral activity of a single drug for multiple subgenomic viral replication systems at once. Such a combination would result in the use of less candidate drugs and other required materials, such as media. The expectation of success would have been reasonable in determining optimal incubation times and multiple target screening of a single drug, given the techniques are well described and commonly used by the ordinary artisan. Furthermore, Olivo et al recites the following regarding the requirements of this method in preparing a single cell culture: "the preparation of the cells requires two separate steps (electroporation of the replicon followed by puromycin selection and plasmid transfection), but once the cells are prepared, the protocols for virus inoculation, sample processing, and data readout are quite simple" (see page 20). Olivo et al suggest that this approach could be used in screening antiviral drugs and in evaluating the efficacy of vaccines. Also, this approach may successfully apply to many different viruses by incorporating virus-specific cis and trans-acting factors into the assay (page 20). Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Horning whose telephone number is 571-272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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